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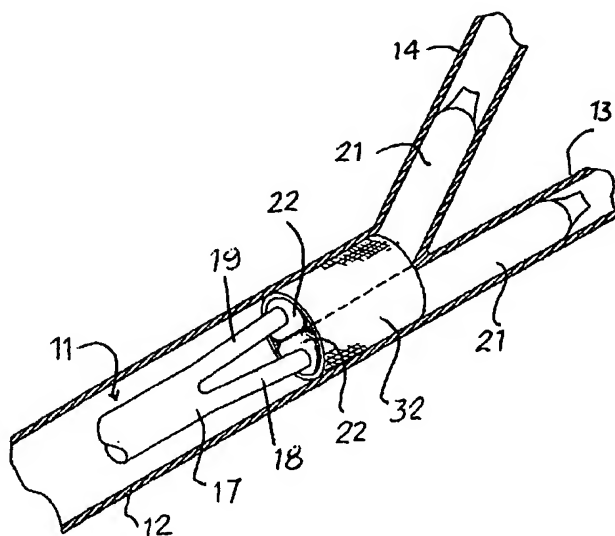
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(54) Title: CATHETERS WITH BIFURCATIONS AND AN INFLATABLE BALLOON ON EACH BRANCH



(57) Abstract: The invention concerns a catheter for therapeutic or diagnostic treatment and/or for the introduction of stents in zones or vessels with a main shaft having at least one bifurcation, includes a flexible tubular body with a main shaft (15) having a distal part, which divides into two or more secondary branches (18 - 20), and an inflatable stretched balloon (21) associated with each of said secondary branches (18 - 20). Each balloon is crossed lengthways by a guide wire, exiting from the catheter either from the proximal part of the latter or from the relevant secondary branch. The proximal part of each balloon is narrowed having a cylindrical, semi-cylindrical or conical part on an axis or off-centre in respect to the distal part, possibly enclosed in a limited expansion sleeve.

CATHETERS WITH BIFURCATIONS AND AN INFLATABLE BALLOON ON EACH BRANCH

5 Field of the invention

This invention concerns the field of catheters in general and refers in particular to a catheter assembly for therapeutic or diagnostic treatment and for introducing stents in bifurcated zones or vessels.

State of the Art

10 A variety of catheters each comprising a flexible tubular body with a distal end, having at least one inflatable balloon and housing at least one longitudinal lumen for inflating a fluid in the balloon and other lumen for guide elements and/or further functional components are well known.

In some catheter used in intravascular or coronary treatments where
15 bifurcation of the vessel trunk is involved, a catheter may be made up of a main shaft with one or more branches, an elongated inflatable balloon on each branch and a guide wire passing lengthwise in each branch and respective balloon. A catheter with a structure as indicated is however open to improvement.

20 Objective and Summary of the Invention

One of the objectives of this invention is in fact to improve the structure of catheters with one or more bifurcations along a main shaft and in particular the configuration of the balloons to facilitate their adaptation and set up in the
respective parts of the vessels they have to occupy during treatment.

25 The objective of the invention is achieved by a catheter having two or more bifurcations at the distal end of a main shaft and an inflatable balloon

associated with each branch, wherein a guide wire passes lengthways through each balloon, this guide wire exits the catheter at the height of the proximal end or at the height of the respective branch with balloon, for a rapid change of each wire in the proximal or distal parts of the catheter, and
5 wherein at least one balloon has a proximal section narrowed with respect to its distal part.

When used, for example in angioplasty or stenosis of a duct or vessel with bifurcations, the proximal parts of the balloons on the bifurcated catheter usually fit into the trunk of the vessel to be treated near the point of bifurcation,
10 remaining close to each other, whereas the distal part of each balloon fits into a relevant branch of the bifurcation of the trunk of the vessel. Normally the trunk of a vessel is wider than each bifurcation branch and it can happen that the sum of the cross-sections of the bifurcation branches is greater than the cross-section of the trunk of the vessel. So, firstly the balloons must be
15 calculated and be able to inflate in the section of the branch where they are required to expand. On the other hand, however, if the balloons are the same size along all their length, their proximal parts, which remain in the trunk of the vessel, when inflated, tend to position themselves at a tangent one to the other and on expanding exercise a force predominantly on the diametrically
20 opposite parts of the trunk of the vessel with the risk of causing improper local dilation of the wall of the latter.

In other words, if each balloon has the correct size in order to fit its distal part in the relevant bifurcation branch, it cannot be certain that the volumes of the proximal parts of the balloons which remain side by side inside
25 the trunk of the vessel itself added together may be excessive and damage

the vessel.

Precisely, in order to avoid this drawback the proximal part of at least one or each balloon according to the invention is narrowed in respect to the distal wall so that the side by side proximal parts of the contiguous balloons
5 become compatible with the dimensions of the trunk of the vessel being treated.

Once more to avoid the abovementioned drawback, the proximal parts of the contiguous balloons may be housed inside a sleeve made of a limited expansion flexible or semi-flexible material compatible with the cross-section
10 of the trunk of the vessel.

In this case, the proximal ends of the balloons are compelled in the sleeve and when they dilate they are obliged to remain within its cross-section once it has reached maximum expansion. This condition enables above all the radial forces to be spread evenly along all the wall of the trunk of
15 the vessel being treated.

Brief description of the drawings

Greater detail of the invention will become clear from the continuation of the description made with reference to the enclosed indicative and non-limiting drawings, in which:

20 Fig. 1 is a view of an example of a catheter with a distal bifurcation with guide wires exiting from its proximal part;

Fig. 2 is a view of a catheter with a similar distal bifurcation, but with guide wires exiting at the height of the bifurcations;

Fig. 3 is a view of the catheter in Fig. 1 or 2 inserted into a vessel with a
25 bifurcation;

Fig. 4 is a view of an example of a catheter with three distal ramifications;

Figs. 5, 6, 7, 8 are views of further different configurations of balloons for catheters according to the invention;

5 Fig. 9 is a view of the ends of two balloons of a bifurcated catheter; and

Fig. 10 is a view of a catheter with the proximal part of the balloons enclosed in a limiting expansion sleeve.

Detailed description of the invention

In the drawings, a catheter 11 is represented to be used, for example,
10 in the treatment of coronary vessels having a main vessel trunk 12 which divides into at least two secondary branches 13, 14, -Figs.3 and 10.

The catheter 11 is made up of a flexible tubular body which comprises a main shaft 15 having a proximal portion 16 connectable to an usual coupling or connector – not shown – and a distal portion 17 which divides into two
15 secondary branches 18, 19, as shown in Figs. 1 and 2, or even three branches 18, 19 and 20, as shown in Fig. 4.

Each of the two or three secondary distal branches 18, 19, 20 has an inflatable/collapsible balloon 21 with a proximal part 22 attached to relevant secondary branch and a distal part 23. The secondary distal branches can be
20 the same or different in length, symmetric or asymmetric with respect to the main shaft 15. Also, the balloons can be the same or different from each other.

The main shaft 15 of the tubular body of the catheter contains at least one insufflation lumen which branches and continues in each of the
25 secondary distal branches 18, 19, 20 to deliver a inflating fluid into each of the

balloons 21.

A guide wire 24 can pass lengthways through each balloon 21 and either exit near the connector or depending on needs, from the distal part 23 of the balloon itself or from a relevant lumen in the body of the catheter.

5 The guide wire can 24 exit from the relevant guide lumen through an opening 25 provided in the proximal part of the main shaft 15 of the body of the catheter – Fig. 1 and 4 – or through a lateral opening 26 provided in the corresponding secondary branch –Fig. 2.

Each balloon 21 may be the same shape and have the same cross-
10 section for its whole length as shown in the examples given in Fig. 1 – 4. But, preferably and in order to make better use as referred above, the proximal part 22 of at least one balloon is narrowed, that is to say with a smaller cross-section in respect to the distal part 23.

The narrowed proximal part 22 of the balloon can be in axis, aligned
15 with the distal part and, when inflated, said narrowed part may have a cylindrical shape, as indicated in 27 in Fig. 5, or conical shape, as indicated in 28 in Fig. 6 or also semi-cylindrical shape as in Fig. 9.

The narrowed proximal part 22 can also be off-centre, that is not aligned with the distal part as shown in 29 of Fig. 7.

20 One or every balloon 21 can have a narrowed proximal part 30 with a cylindrical shape and a conical distal part 31 as shown in Fig. 8.

In each of the shapes formed, the proximal parts 22 of the contiguous balloons, whether narrowed or not, may be enclosed in an external sheath or sleeve 32 as shown in Fig. 10. The sheath or sleeve 32 is made of a flexible
25 or semi-flexible material, and has however limited and controlled expansion to

contain the expansion of the proximal parts of the balloons and when dilated, the sheath or sleeve 32 fits snugly against the wall of the trunk of the vessel adjacent to the bifurcation, leaving the distal parts of the balloons free to adapt to the relevant secondary branches of the vessel. In other words, the sheath
5 or sleeve 32 could have greater resistance to deformation than the vessel being treated.

Worthy of note is the fact that the catheter described above provided with at least two branches, each carrying a balloon, can also be used to introduce stents, that is to say, as a means of introducing, positioning and
10 expanding stents in the case of stenosis in zones, ducts or vessels with bifurcations along the main vessel trunk. The stent may be placed on one or both the balloons and may be Y bifurcated with branches dividing on the distal parts of each balloon.

"CATHETERS WITH BIFURCATIONS AND AN INFLATABLE BALLOON
ON EACH BIFURCATION"

C L A I M S

- 5 1. A catheter for therapeutic or diagnostic treatment and for the introduction of stent in zones or vessels having a main trunk with at least one bifurcation, characterised by a flexible tubular body with a main shaft (15) having a proximal portion connectable to a coupling or connector, and a distal portion which divides into two or more secondary branches (18 – 20); by an
10 inflatable elongated balloon (21) associated with each of said secondary branches (18 – 20) and having a proximal part (22) attached to relevant secondary branch and a distal part (23), and wherein each balloon is crossed lengthways by a guide wire, said guide wire exiting from the catheter either from the proximal part of the latter or from the relevant secondary branch with
15 balloon, and the proximal part of at least one balloon is narrowed in respect to the distal part.
2. Catheter according to claim 1, wherein the adjacent proximal parts (22) of the balloons are enclosed in a limited dilation and expansion sheath or sleeve (32) said sheath or sleeve being formed of a flexible or semi-flexible
20 material or having a higher resistance to deformation than the vessel being treated.
3. Catheter according to claims 1 or 2, wherein the secondary branches (18 – 20) of the catheter body are of the same or different lengths and are either symmetrical or asymmetrical in respect to the main shaft (15)
- 25 4. Catheter according to claims 1 or 2 and 3, wherein the balloons (21) on the secondary branches (18 – 20) of the catheter body are either the same or

different from each other and each has a uniform or variable longitudinal section.

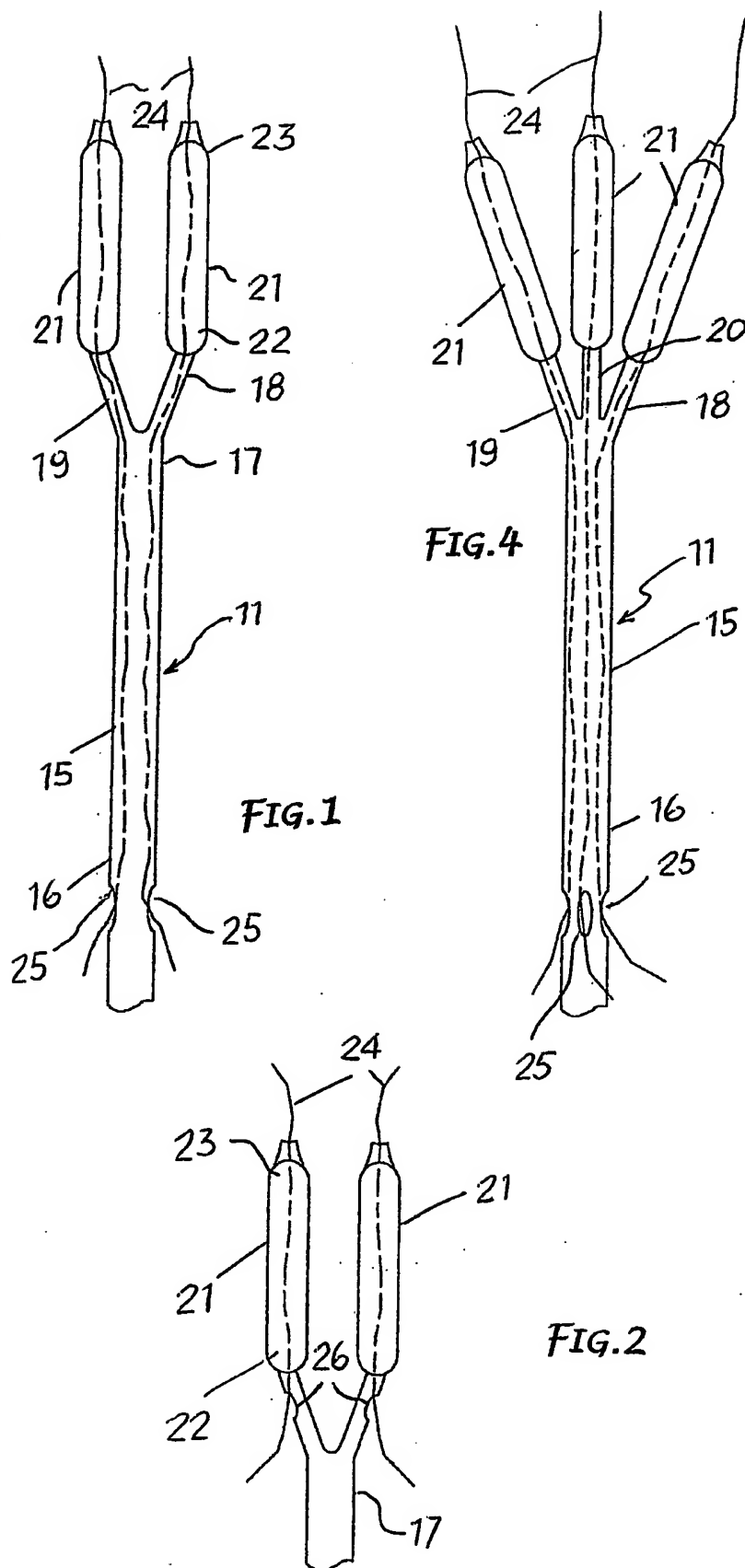
5. Catheter according to the previous claims, wherein the narrowed proximal part (22) of the balloon is axial in respect to the distal part (23).

5 6. Catheter according to claim 5, wherein the narrowed proximal part (22) of the balloon is either cylindrical (27) or semi-cylindrical (29).

7. Catheter according to claim 5, wherein the distal part (23) of the balloon is conical (31).

8. Catheter according to claim 5, wherein the proximal part (22) of the
10 balloon is conical (28).

9. Catheter according to claims 1 and 4, wherein the narrowed proximal part (22) of the balloon is off-centre (29) in respect to the distal part (23).



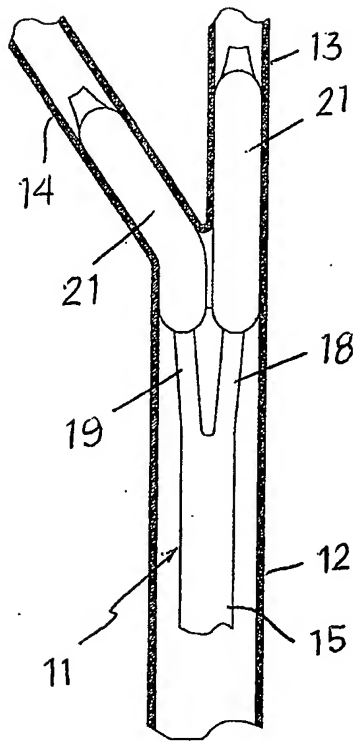


FIG. 3

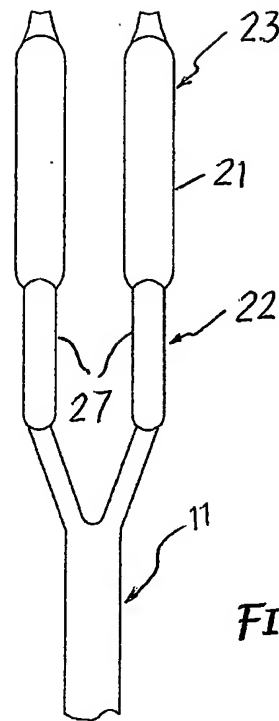


FIG. 5

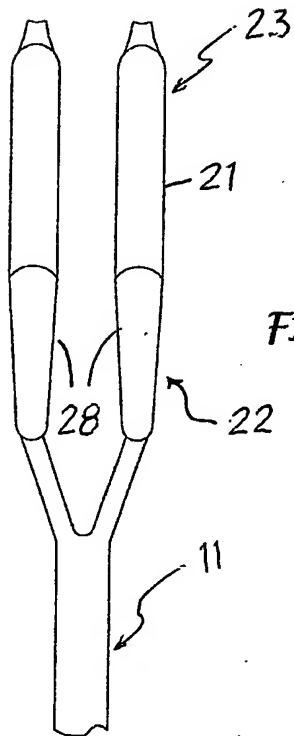


FIG. 6

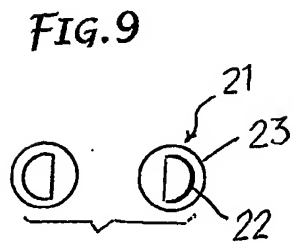


FIG. 9

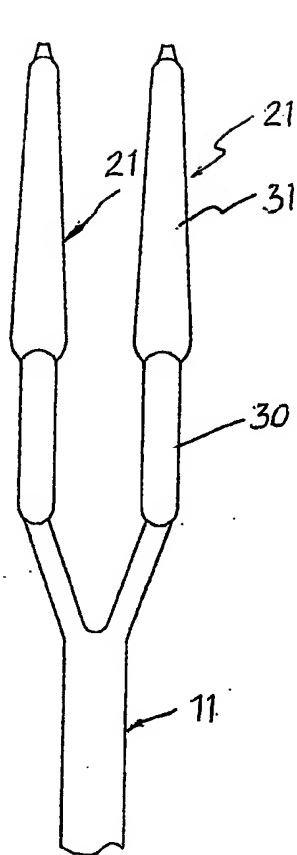


FIG. 8

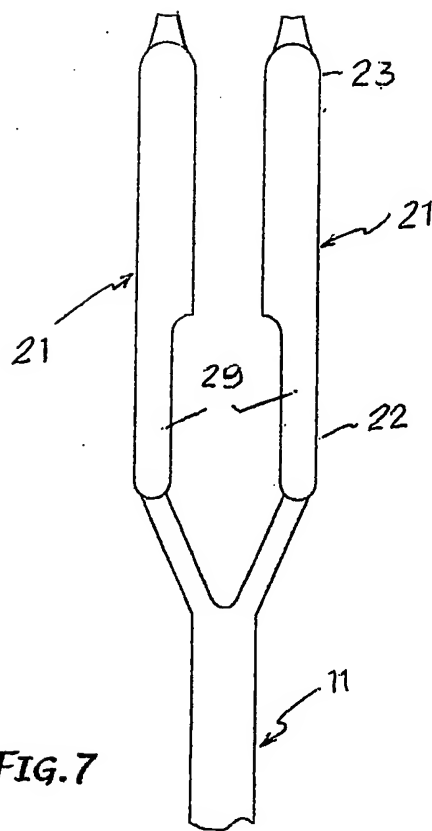


FIG. 7

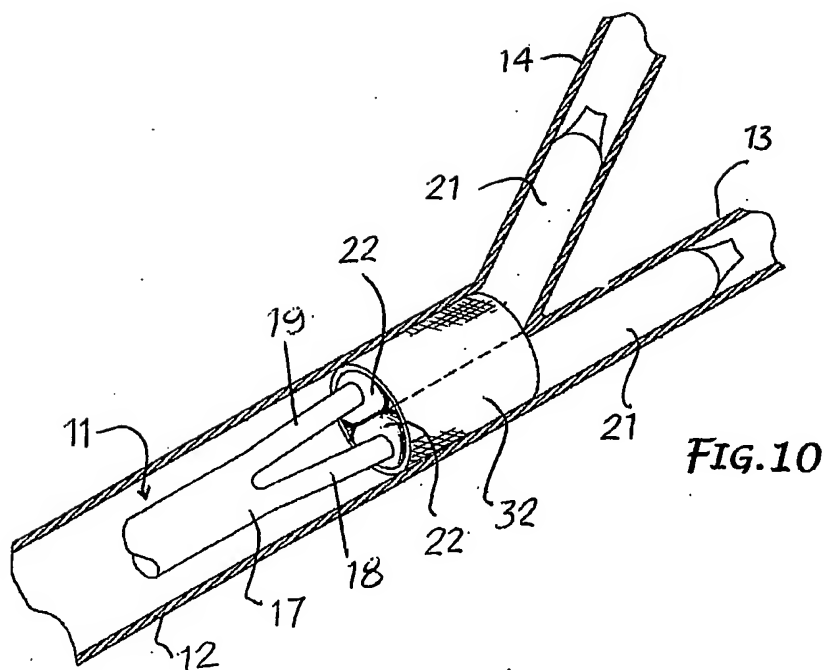


FIG. 10

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IT 03/00085

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 347 023 A (BARD INC C R) 20 December 1989 (1989-12-20) column 1, line 37 -column 2, line 13 column 4, line 29-54 column 6, line 21-28; figures 1,3 -----	1,3-9
X	US 5 669 924 A (SHAKNOVICH ALEXANDER) 23 September 1997 (1997-09-23) column 9, line 51 -column 10, line 7; figures 1,9,18,19A,19B -----	1,3-9
A	US 2001/008976 A1 (WANG LIXIAO) 19 July 2001 (2001-07-19) figures 7,9 -----	3-9

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Publication No

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 0347023	A	20-12-1989	US 4896670 A	30-01-1990
			CA 1315632 A1	06-04-1993
			EP 0347023 A2	20-12-1989
			JP 2013470 A	17-01-1990
US 5669924	A	23-09-1997	AU 7472796 A	15-05-1997
			WO 9715346 A1	01-05-1997
US 2001008976	A1	19-07-2001	US 6290485 B1	18-09-2001
			US 5980532 A	09-11-1999
			US 5749851 A	12-05-1998
			US 2002183780 A1	05-12-2002
			US 6352551 B1	05-03-2002